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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,985	01/13/2004	Brian Blischak	02-036 US	2245

35320 7590 05/30/2008

ADVANCED NEUROMODULATION SYSTEMS, INC.
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EXAMINER	
BHATIA, AARTI	
ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
05/30/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/755,985	BLISCHAK, BRIAN	
	Examiner	Art Unit	
	AARTI BHATIA	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-26, 49, and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *18-26, 49, and 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/13/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the third Office Action based on the 10/755,985 application filed on 1/13/2004. Claims 18-26 and 49-54, as amended on 1/23/2007, are currently pending and have been considered below.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first reservoir, the second reservoir, the actuator, and the one-way valve must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18-26 and 49-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The features in the claims are not shown in the drawings, see drawings rejection above.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 18-26, 49, and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,139,397 to Tucker et al. in view of U.S. Patent No. 5,700,245 to Sancoff et al.

Tucker discloses a method of operating an implantable infusion drug pump, comprising: storing infusate in a main reservoir of the implantable infusion drug pump, wherein a substantially constant fluid pressure is provided to the infusate in the main reservoir; driving infusate from the main reservoir through a flow restrictor and out through a discharge port of the implantable infusion drug pump at a substantially constant basal infusion rate, including delivering to a treatment area a basal flow dosage of the pharmaceutical fluid from a constant flow pump (column 2, lines 16-21), which does not comprise an electrical motor or electrical power supply (column 2, lines 34-35); providing a temporary bolus infusion rate in response to patient manipulation (either manually or magnetically) of an actuator of the implantable infusion drug pump (column 2, lines 22-34), wherein the bolus infusion rate is provided simultaneously to the basal infusion rate, wherein the implantable infusion drug pump comprises at least one one-way valve (column 4, lines 53-59; column 8, lines 21-33) that enables the secondary reservoir to be filled without being subjected to a flow rate limitation of a flow restrictor (72) of the implantable drug infusion pump.

Tucker fails to teach the specifics of the bolus delivery.

Sancoff teaches a method comprising: wherein the providing a temporary bolus infusion rate comprises manually applying pressure (figure 2) to a working fluid contained in an actuator (10) associated with an implantable pharmaceutical fluid delivery device (5), wherein the implantable pharmaceutical fluid delivery device comprises a first fluid reservoir (27) and a second fluid reservoir (17), thereby causing a flow of the working fluid into the first fluid reservoir (figure 2 with respect to figure 1); delivering to the treatment area a first dosage of pharmaceutical fluid (20) from the second fluid reservoir by transferring pressure from the working fluid in the first reservoir to the pharmaceutical fluid in the second reservoir (abstract), wherein the working fluid (gas) and the pharmaceutical fluid (20) are different fluids; comprising drawing working fluid from the first fluid reservoir into the actuator, causes a filling of the second fluid reservoir (17) with pharmaceutical fluid (20), wherein the delivering to the treatment area a first dosage comprises drawing the working fluid (gas) into the actuator from the first fluid reservoir thereby causing pharmaceutical fluid to be expelled from the second fluid reservoir wherein the actuator is selected from the group consisting of a compressible button and a bulb (60), driving infusate from the main reservoir is performed by an elastomeric diaphragm (25); wherein the secondary reservoir is adapted to hold a maximum fluid volume that is greater than a maximum fluid volume of the working fluid reservoir (see figure 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Tucker with the bolus delivery method of Sancoff, since the working fluid of Sancoff provides for a very controlled delivery rate.

Further it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate piston and cylinder devices into the fluid reservoirs as these are well-known features in the art (see for example U.S. Patent No. 6,736,795 to Michel).

Response to Arguments

7. Applicant's arguments with respect to claims 18-26 and 49-50 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763
/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763